510(K) SUMMARY

NOV 2 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: K123185.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

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Contact Person:
Zhai Pei
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: August 28, 2012

2. Device Name: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Classification
Regulatory Class: II
Review Category: Tier II
21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, PW-Mode, CW mode, Color-Mode, Color M-Mode, Power/Dirpower Mode, TDI mode, 3D/4D mode,

Elastography or the combined mode (i.e. B/M-Mode).This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 3 MHz to 10.0 MHz.

4. Intended Use:

The DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

5. Comparison with Predicate Devices:

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Number
1	Mindray	DC-8/DC-8PRO/DC-8 CV /DC-8 EXP/DC-8S	K113647
2	Mindray	DC-7	K103583 K101041
3	Mindray	DC-T6	K110199
4	Mindray	Z6	K122010
5	SIEMENS	ACUSON S2000	K112596
6	SIEMENS	SONOLINE Antares Ultrasound Imaging System	K050034

They have the similar technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate devices.

6. Non-clinical Tests:

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC

60601-2-37, IEC 62304, IEC 62366,UL 60601-1, ISO14971, UD 2, UD 3 and ISO 10993-1.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 21 2013

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K123185
Trade/Device Name: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: September 27, 2012
Received: September 10, 2012

Dear Mr. Rongero:

This letter corrects our substantially equivalent letter of November 2, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-2E	D8-3E
C7-3E	V11-3E
L12-3E	C11-3E
L14-6NE	DE10-3E
L14-6WE	V11-3BE
P4-2E	V11-3WE
D6-2E	L7-3E

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Ms. Lauren Hefner at (301) 796-6881.

Sincerely Yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostic
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K123185

Device Name: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Indications For Use:

The DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health(OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

Diagnostic Ultrasound Indications For Use Format

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: N/A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2,3, 4,6,7
	Abdominal.	P	P	P	P	P	P	P	Note 1, 2,3, 4,5,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,3, 4,5,6,7
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Intravascular								
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Other (Specify***)	P	P	P		P	P	P	Note 1, 2, 4,6,7

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: C5-2E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: C7-3E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Other (Specify***)								

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes–B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: L12-3E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Other (Specify***)								

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: L14-6NE

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2, 4,6,7
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,6,7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2, 4,6,7
	Other (Specify***)								

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: L14-6WE

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2, 4,6,7
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,6,7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2, 4,6,7
	Other (Specify***)								

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

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Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: P4-2E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes-B+M、PW+B、Color+B、Power+B、PW+Color+B、Power+PW+B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: D6-2E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note1,2, 3, 4,6
	Abdominal	P	P	P		P	P	P	Note1,2, 3, 4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note1,2, 3, 4,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: D8-3E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note1,2, 3, 4,6
	Abdominal	P	P	P		P	P	P	Note1,2, 3, 4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note1,2, 3, 4,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: D8-3E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note1,2, 3, 4,6
	Abdominal	P	P	P		P	P	P	Note1,2, 3, 4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note1,2, 3, 4,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color+B、Power+B、PW+Color+B、Power+PW+B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: V11-3E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	P	P	P		P	P	P	Note 1, 2, 4,6,7

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes–B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System
Transducer: C11-3E
Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Cardiac Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System
Transducer: DE10-3E
Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 3,4,6
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 3,4,6
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 3,4,6
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes–B+M、PW+B、Color + B、Power + B; PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: SmartUD

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System
Transducer: V11-3BE
Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4,6,7

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B、

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System
Transducer: V11-3WE
Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4,6,7

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes- B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B,

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: SmartSD

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185

System: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System
Transducer: L7-3E
Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1,2, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2, 4,6,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2, 4,6,7
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2, 4,6,7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2, 4,6,7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2, 4,6,7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B,

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123185